

Notice of Allowability

Application No.

09/926,484

Applicant(s)

MEIER ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 29 July 2005.
2. ☒ The allowed claim(s) is/are 1-19.
3. ☒ The drawings filed on 09 November 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 8/23/02; 4/17/03; 5/28/03; 9/8/03; 10/13/04; 5/16/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

THURMAN K. PAGE
SUPERVISOR, PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Final Response, Request for Reconsideration and Applicant's Arguments/Remarks, all filed 07/29/05 is acknowledged.

Claims 1-19 are pending. Claims 1-19 are allowed.

EXAMINER'S AMENDMENT

The application has been amended as follows:

In the Specification:

On page 3, line 15, the following has been inserted:

"Brief Description of the Drawings"

Figure 1 illustrates a release curve of KCl crystals coated with inventive dispersion.

Figure 2 illustrates a release curve of diprophylline matrix tablets.

Allowable Subject Matter

Claims 1-19 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Tomoaki *et al.* - JP 01-113322 & Lippmann *et al.* - US Pat. No. 4,259,315) do not disclose nor fairly suggest a dispersion as instantly claimed having a nonionic emulsifier having an HLB of from 15.2 to 17.3. Rather the

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prior art (Tomoaki *et al.*) teaches an anionic emulsifier, such as sodium dodecyl sulphate and the prior art (Lippmann *et al.*) teaches only a general disclosure of a non-ionic emulsifier having an HLB value of greater than 10. The prior art fails to disclose or suggest the instant HLB range of from 15.2 to 17.3 and fails to recognize that the instant HLB range of from 15.2 to 17.3 offers a distinct influence on the crystallization behavior of the emulsifier. The instant dispersion having an HLB of from 15.2 to 17.3 demonstrates superior and unexpected results as well as an improvement over prior art formulations because the HLB range claimed provides for non-crystallization of the emulsifier and stability of the emulsion formulation. Applicants have discovered that if the HLB is above the claimed range, the emulsifiers crystallize. Contrastingly, if the HLB is below the claimed range, the emulsifiers are unable to stabilize the emulsion sufficiently. Therefore, the instant HLB (from 15.2 to 17.3) claimed provides for non-crystallization of the emulsifier as well as stability of the emulsion formulation. Accordingly, in view of the improvements demonstrated by the instant invention and the deficiencies of the prior art, the instant invention is rendered non-obvious and *patentable* over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Note: The pending/patented application nos. listed on the IDS filed 8/23/02, 4/17/03, 5/28/03, 9/8/03, 10/13/04 & 5/16/05 have been considered, are made of record, but will not be printed on the patent issue publication.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh



Patent Examiner

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August 11, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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